APPENDIX A

[0001] FIELD OF THE INVENTION

[0002] The present invention generally relates to an implant useful for treating rotational malfunction of the spinal column, and especially Idiopathic Scoliosis. The implant comprises a plate and at least two anchors, and is adapted for applying progressive rotational force against the scoliotic curve so as to correct the curvature over a period of time.

[0003] BACKGROUND OF THE INVENTION

[0004] Scoliosis may be defined as deviation of normal spine in all three directions or planes: frontal (coronal), lateral (sagittal) and transversal (axial). In other words, scoliosis is a complex 3D deformation of the trunk, spine and rib cage. Clinically, the most prominent feature of this complex deformity is sideward curvature of the trunk accompanied by the hump of the rib. The most common variant of a scoliotic deformity is Idiopathic Scoliosis and particularly the adolescent type that may effect up to 3% of the adolescent population. The exact cause of this problem is still unknown, which explains the term "Idiopathic" for this type of scoliosis. The list of clinical problems associated with scoliosis goes far beyond the pure cosmetic complaints. It includes distortion of abdominal and chest organs and therefore alteration of their functional capabilities, alteration of normal gait with associated pelvic obliquity and many other functional and social difficulties.

[0005] Apart from congenital scoliosis, which is caused by congenital anomalies of spinal structure, for idiopathic scoliosis no congenital anomalies of vertebras or rib cage are identified. This may partially explain the fact that, until the present time, despite numerous attempts, no animal model of idiopathic scoliosis has been made without purposeful alteration of vertebral structure. Therefore, evaluation of the new methods for treatment has been complicated and empirical, mainly based on the personal experience, and beliefs of the surgeon. In fact, the principals of treatment of scoliosis have remained basically unchanged for the last 70 years. Historically, idiopathic scoliosis treatment

began with attempts at manual correction using different types of orthotic holding devices, so that the fusion of spinal column *in situ* was achieved. Treatment modalities then advanced to acute surgical correction of the deformed spine. Today, the principles of this surgical correction include two basic steps: first, acute correction of spinal deformity during surgery and insertion of a holding device, and second, solid fusion of vertebral bodies in the corrected position, by insertion of a bone graft during the same surgical procedure.

[0006] Though Idiopathic Scoliosis is not an acute illness, over time, the vertebrae become secondarily deformed. Surgeons who treat scoliosis are well-aware of the deformed shape of scoliotic vertebrae, and the deformity is especially prominent using computer tomography evaluation. Apical vertebrae are the most deformed and they appear twisted on the axial CT images.

[0007] Different types of holding devices have been introduced for treating idiopathic scoliosis. All of them are based on manual correction of deformity during the surgery and insertion of holding rods or plates engaged to the vertebral body or vertebral prominences by different anchoring devices. The classical example of such an approach is the worldwide known Harrington's rods instrumentation (Luque, Cotrel-Dubosset, Zielke). Later, a segmental instrumentation of different types was developed. Debousset and Cotrel have suggested an instrumentation system that is currently considered as a gold standard instrumentation and includes correction in all three planes, but correction is performed acutely and rotational component of correction is limited (See "Instruments in the Treatment of Vertebral Column Deformities", Orthopade, 1989, 18:118-127). Only recently have investigators began to look for dynamic properties of such devices and start using different types of metalwork with elastic properties, but these new inventions are still based on acutely performed correction and are aimed for preservation of this correction by holding devices until biological fusion of spinal column is achieved. Other efforts are aimed at minimizing the fused segment of deformed spinal column and thus to increase the movement of free spinal segments.

[0008] All of these methods are characterized by an extensive traumatic nature and have a relatively high morbidity rate. Furthermore, spinal instrumentation usually involves massive amounts of metal, which remains in the body for many years and or for life. Recently, investigators have begun to realize the detrimental side effects of long-standing metal implants on human body. It is acknowledged that removal of instrumentation is a traumatic procedure, especially from a fused spine having distorted anatomy. Lastly, the harmful side effects caused by the partial dissolving of the metallic parts and compositions are well-recognized.

[0009] Unfortunately, a device and method for treating Idiopathic Scoliosis which effectively allows for some preservation of natural spinal movement without decreasing the reinforcing properties of the device does not yet exist. Such a device, exhibiting predetermined 3D rotational abilities for progressively but effectively correcting the curvature of the spine, is sorely needed.

[0010] SUMMARY OF THE INVENTION

[0011] It is hence the aim of the present invention to provide an implant useful for treating rotational malfunction of the spinal column wherein implant is adapted to apply pure rotational progressive forces. The implant thus operates to correct deformation of the spine in a fusionless manner.

[0012] The present invention relates to an implant for treating rotational malfunction of the spinal column, especially for the treatment of idiopathic scoliosis, comprising:

[0013] a plate having a first end and a second end; and

[0014] at least two anchors, for anchoring the first and second ends of the plate to the upper and lower apex, respectively, of the scoliotic curve of the spine.

[0015] The plate is formed of a material having inherent springiness, such that, following twisting of the plate to a predetermined degree and implantation of the plate onto the spine using the anchors, the plate functions to apply a progressive de-rotational force on the spine, so as to correct the curvature of the spine in a gradual manner.

[0016] According to preferred embodiments of the present invention, the anchor comprises anchoring means, for anchoring an anchor to a single vertebra of the spine, and connecting means, for connecting the anchor to the first or second end of the plate.

[0017] Preferably, the anchoring means comprises at least one hook. More preferably, the anchoring means comprises two hooks. Additionally, the anchoring means may comprise at least one clasping member. In some preferred embodiments, the anchoring means comprises a first portion and a second portion. Each of these portions comprises a hook and clasping means, which, in combination with one another, serve to effectively fix the anchor to a vertebra of the spine.

[0018] Further according to preferred embodiments of the present invention, the connecting means comprises at least one screw. Additionally, according to preferred embodiments of the present invention, the connecting means comprises a connecting plate. Preferably, each portion of the anchor couples with the connecting plate, such that, the anchor is able to securely accommodate one end of the plate therein.

[0019] According to preferred embodiments of the present invention, the plate is formed from a stainless steel material having inherent springy properties, such as are well-known for use in automobiles or other machinery. Prior to installation in the spine, the surgeon twists the plate to a predetermined degree and the plate is implanted in the spine in this twisted manner. Once implanted, the plate progressively untwists ("de-rotates"), thereby effectively applying a rotational force on the spine, through the anchors.

[0020] Preferably, the clasping member of the anchor is adapted for clasping the spinous process portion of a single vertebra while the hook of the anchor is adapted for hooking onto the transverse process of a vertebrae. Thus, in embodiments including two clasping members, and two hooks, the single vertebrae is gripped at four different locations.

[0021] According to preferred embodiments of the present invention, the plate has a length that is adapted to extend from the upper scoliotic apex to the lower scoliotic apex. Preferably, the plate has a substantially elongated configuration selected from one of the group consisting of: a polygon form, a rod-like form, a sheet-like form, a helical form, a spring, a frame comprising parallel enforcing structures, a bundle of fibers, a screw-like member, a network of warp and weft enforcement, or a porosive matrix.

[0022] BRIEF DESCRIPTION OF THE FIGURES

[0023] In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of a non-limiting example only, with reference to the accompanying drawings, in which:

[0024] Fig. 1A schematically presents a 3D view of the best mode of the implant according to the present invention and Fig. 1B illustrates the main parts of the implant;

[0025] Figures 2a-2k schematically present various possible preferred embodiments for the plate of the implant of the present invention;

[0026] Fig. 3 schematically presents a 3D view of an anchor, for anchoring the plate of the implant to the spine, according to one embodiment of the invention;

[0027] Fig. 4 schematically presents a 3D view of an anchor, for anchoring the plate of the implant to the spine, according to another embodiment of the invention;

[0028] Figure 5 schematically presents a cross section of a single vertebra of the spinal column;

[0029] Figures 6a and 6b schematically present cross sections of vertebrae of the spine, with an anchor attached thereto;

[0030] Figures 7a and 7b schematically present the implant of the present invention installed onto the spine; and,

[0031] Figures 8a, 8b, and 8c schematically present views of the coronal, longitudinal and sagittal movements of the plate of the implant of the present invention.

[0032] DETAILED DESCRIPTION OF THE INVENTION

[0033] The following description is provided, along all chapters of the present invention, so as to enable any person skilled in the art to make use of the invention and sets forth the best modes contemplated by the inventor for carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide an implant for treating Idiopathic Scoliosis and a method for using the same.

[0034] It is hence in the core of the invention to provide implant an adapted to be installed and later removed from the spine, generally useful for treating rotational malfunction of the trunk and/or spinal column, and especially for the correction of Idiopathic Scoliosis. The implant is adapted to apply pure rotational progressive forces on the trunk of mammals and/or their spinal column. The spinal column may be divided into the thoracic spine (e.g., the upper portion) and the lumbar spine (e.g., the lower portion).

[0035] Reference is made now to FIG. 1A, presenting a preferred mode of the present invention. The removable implant comprises a plate (1) having a generally elongated

configuration and a set of anchors (2) and (3). The plate (1) corrects the curvature of the spine by applying pure rotational forces through means of the anchors (2 and 3), which are physically held by both the thoracic and the lumbar portions of the spinal column. Plate (1) is preferably formed to have a length so as to extend longitudinally from both the upper and lower apexes of the scoliotic curve (the length of the plate may thus vary between patients). At or near each apex, plate (1) is attached to the spinal column by an anchor (2,3). It is appreciated that at no other locations is plate (1) connected to the spine. In instances of scoliosis where there are more than two apexes, there are a corresponding number of anchors.

[0036] It is appreciated that different types of anchors are possible for anchoring the plate (1) to the vertebra of the spine. Generally, each anchor includes anchoring means, for anchoring the anchor to the vertebrae, and connecting means, for connecting the anchor to the plate. In the anchors (2,3) illustrated in Figure 1A, the anchoring means comprises a pair of hooks. In the triangular-shaped anchor (4) shown in Figure 1B, the anchoring means comprises a screw which is screwed into the vertebrae. It is appreciated that other types of anchor assemblies are possible as well, for performing the function of anchoring the plate to the spinal column.

[0037] It is also noted, as seen in Figure 1A, that most of the length of the plate (i.e., the length in between the two anchors) is free from attachment to the spine. Plate (1) is preferably formed of a stainless steel material having inherent springiness. Prior to implantation in the spine, the plate is twisted (11) to a predetermined degree (the degree of twisting is determined at least partially by the extent and direction of deformation of the spine so as to exert a rotational force opposite to this). Once implanted, the plate "untwists" in the opposite direction to ultimately return to the non-twisted configuration (5, 8), while simultaneously and gradually exerting a rotational force on the spine via the anchors. Stoppers (6,7) seen in Fig. 1B, facilitate connection of the plate to the anchors.

[0038] The shape of the aforementioned plate may be designed in various forms. Reference is made now to FIG. 2A to 2K, presenting various forms of the plate. FIG. 2A presents a rod-like form having a circular cut (21). FIG. 2B presents a square plate, having a square cut (22). FIG. 2C presents a polygon form having a polygon cut (23). FIG. 2D presents a helical form (e.g., a spring, a triple helix etc). FIG. 2E presents a male thread screw having a circular cut (21) and helical screw-groves (24). FIG. 2H presents a similar parallel enforcing structure (25 [shown separately in FIG. 2F] additionally comprising a network of warp and weft enforcement (25A and 25B [shown separately in FIG. 2G]). The mash of said network may varied and differ from case to case. FIG. 2I presents a porosive matrix (26). It is acknowledged in this respect that any combination of the above is possible.

[0039] It is further in the scope of the present invention wherein the surgeon has accurate means to regulate the torque applied on the spinal column. Hence, reference is now made to FIG. 2J, presenting a schematic view of a bundle of elastic fibers (27). The amount, the type and the size of the fibers can be altered so that a particular torque force is produced. Similarly, reference is made now to FIG. 2K, schematically presenting another preferred embodiment of the present invention, wherein a plurality of linear-like members (28A, 28B etc) are arranged in a stack. By addition or removal of one or more of said members, the surgeon can regulate the desired moment, suitable for the patient at a given time or stage.

[0040] It is well in the scope of the present invention wherein the plate as defined in any of the above is made of stainless steel, such as 304 or 316 Stainless Steel; and alternatively or additionally, comprising composite materials, shape memory alloys, such as Nitinol shape memory polymeric compositions, or any combination thereof.

[0041] It is still in the scope of one preferred embodiment of the present invention wherein the plate dimensions is in the range of about 150 mm.X.350 mm (length), about 10 mm X.30 mm (width), and about 0.5 mm X 1.5 mm (thickness). The plate is

preferably set to apply a moment of about 5 lbs/cm to 150 lbs/cm. The amount of twisting of the longitudinal plate is in the range of about 40 degrees to 90 degrees.

[0042] Reference is now made to FIG. 3, presenting one preferred embodiment for an anchor. The anchor comprises anchoring means (a) having a first portion (15) and a second portion (16), for anchoring the anchor to a vertebra of the spine. Each portion (15, 16) includes a hook (30a, 30b) and clasping members (37a, 37b), both of which are adapted in shape for gripping at least one vertebrae of the spine (see additionally Figures 6a and 6b). First and second portions (15,16) interconnect with one another via a connecting plate (39), onto which the two portions (15,16) engage by means of slide means (36a, 36b). When mounted thereon, the end of the plate is installed in between the anchor portions (15, 16) and the connecting plate (39) so as to be firmly secured therebetween. Additional means may be used for affixing the plate with respect to the two anchors. It is appreciated that this embodiment presents only one possible scenario for the type of anchor and for the means of attachment to both the spinal vertebrae and the plate. Many other types of anchors could be conceived, as would be evident to those skilled in the art. The anchors may differ in design, for example, according to their destined location in the spinal column or according to the age of the patient, and what is deemed to be the most effective design.

[0043] Reference is made now to FIG. 4, and to another embodiment for an anchor. This anchor also includes left and right portions, each with its own hook (40b), though only one portion (16) has been illustrated. In the embodiment shown, each anchor portion is attached to a connecting plate (49) by means of a screw (49b) and corresponding bores (42b, 43b).

[0044] Reference is made now to FIG. 5, presenting a schematic cross section view of the spinal column, comprising spinous process (51); articular process (52); transverse process (53); podicle (54); vertebral body (55) and lamina (56).

[0045] Reference is made now to Figures. 6a and 6b, presenting schematic cross section views of vertebrae of the spine, with an anchor mounted thereto. Fig. 6a is meant to represent a vertebrae located at the thoracic region of the spine, at the first apex of the scoliotic curve, whereas Fig. 6b is meant to represent a vertebrae located at the lumbar region of the spine, at the second apex of the scoliotic curve. The correctional rotational force applied to the spine due to the de-rotation of the plate is preferably as indicated by arrows (61, 62) (this corresponds to the usual direction of malcurvature present in patients with idiopathic scoliosis), with the upper spine being corrected by curving towards the right (61) while the lower spine is corrected through curving towards the left (62).

[0046] FIG. 6A shows hooks (53,63) gripping the transverse process (53), while the spinous process (51) is clasped by means of clasping members (See 37a, 37b in FIG. 3).

[0047] Reference is made now to FIG. 7B, schematically presenting a top view of the spinal column of a patient having a Idiopathic Scoliosis, e.g., having an upper apex (71) and a lower apex (72) of the scoliotic curve, to be rotationally treated by a means of the implant as defined and described in the present invention. The upper anchor is thus affixed on the spinal column at the apex of the upper scoliotic curve and the lower anchor (1c) is affixed onto the spinal column at the apex of the lower scoliotic curve; the twisted plate (11) extends therebetween, without any other attachment to the spine. FIG. 7a shows the spinal column from the other side.

[0048]

Reference is made now to FIG. 8, presenting a top view of various modes of action of the implant as defined above. Hence, FIG. 8A presents a coronal (side bending) movement in the direction 8A (lateral). FIG. 8B presents a longitudinal movement in the direction 8B (vertical), showing that growth of the spinal column provides no problem for the implant. Finally, FIG. 8C presents a sagittal (flexion-extension) movement in the direction 8C. It is further acknowledged in this respect that the anchors may be provided with shaped

protrusions adapted to provide the aforementioned a coronal, longitudinal and/or any predetermined movement of the linear plate. Said protrusions are preferably characterized by a U or a V contour. The protrusions may function to translate the force applied from the plate to the spine to different suitable directions, as required by the curvature present in the patient. The gap between the two oppositely directed apexes of the protrusions is about equal to the width of the linear plate, with the gap preferably exceeding about 1 mm the width of the linear plate.

[0049] The method of implantation is a sequence of steps as generally described below: (i) exposing the spinal column over the apex of the proximal (upper) scoliotic curve; (ii) implanting the anchors on the upper scoliotic curve; (iii) implanting the anchors onto the lower scoliotic curve; (iv) making the subcutaneous tunnel between the two operating wounds by blunt dissection under superficial fascia; (v) placing the plate into the subcutaneous tunnel; and then (vi) twisting the distal (lower) end of the spring-plate along its longitudinal axis in the opposite direction to the proximal (upper) end of the longitudinal spring-plate.

[0050] The medical procedure additionally comprises various steps, as defined below. First is the step of placing the patient in a prone position. It is acknowledged in this respect that no excessive pressure exists on the abdomen or on the limbs.

[0051] The second step is preparing the patient's back to be operate on, such as by decontaminating the surface with a surgical soap solution for 5 to 7 minutes and then with antiseptic solution. Preferably, the area of the operative site is then draped and commercial available plastic steri-drape is used to seal off the skin.

[0052] The third step is making a straight midline skin incision centered over the apex of the proximal (upper) scoliotic curve. The incision length is approximately along about 2 to 3 spinous processes. Then, the incision is deepened to the level of the spinous processes. The bleeding is controlled with electrocautery.

[0053] After those preparations, the aforementioned method is carried out. For the sake of explanation, the above mentioned steps are now to be underlined and explained. The base part of the apical vertebra is extaperiosteally exposed from each side of it. The practitioner is preferably suggested to confirm the right location by using of image intensifier.

[0054] The extraperiosteal dissection is extended sideways from the spinous process, while keeping the retractors (e.g., Weitlaner retractors) tight at all times. It is preferably suggested to preserve maximum portion of the muscles and ligaments around, until the middle part of the transverse process on each side of the apical vertebra is been exposed.

[0055] The self-retaining retractors are now placed deeper to hold the entire incision open and exposed. The hook part of the anchor is placed by sliding the tip of it under the base of the transverse process. The direction of the hook insertion may be either proximal (cranial) or distal (caudal). The same procedure is subsequently performed on the other side of the vertebra. It is acknowledged that in a case that the surgeon decides to use any other than hook-anchor part, for example screw-anchor part, its placement is performed using standard technique for a perpendicular screw placement.

[0056] The secure placement of the anchors is checked by means of fixating the triangular slope-block part, (e.g., by using a small screw) to the flat surface of the anchor located on the convex side of the scoliotic curve. The anchors are then pushed towards the middle line and to each other until they contact above the spinous process of the apical vertebra and intact supraspinous ligament. As both anchors are in contact, the surgeon is advised to make sure that no ligamental tissue is crushed between their docking parts. In case of entrapment, the anchors can be replaced with higher ones in such a way that their docking parts meet above the tip of the spinous process and supraspinous ligament.

[0057] Now, both anchors are immobilized by placing the connecting plate on the upper flat surfaces of the anchors and loosely fixating the connecting plate by two small screws on each end of it.

[0058] The same procedure is now provided through the separate incision on the level of the apical vertebra of the distal (lower) scoliotic curve with one exception: the connecting plate should be fixed only to one anchor located on the concave side of the scoliotic curve. The surgeon should check that the triangular slope-block is located on the opposite side to the triangular slope-block of the upper anchor assembly, because in case of the double curve the apical parts of the both curves are rotated in the opposite directions.

[0059] The subcutaneous tunnel between the two operating wounds is then provided by a blunt dissection under superficial fascia. The plate is subsequently inserted into the subcutaneous tunnel. The proximal (upper) end of the plate is inserted into the slot under the connecting plate of the anchor assembly and secures the plate to the anchors assembly by tightening of the two small screws. Now the upper part of the plate is secure.

[0060] The distal (lower) end of the spring-plate is twisted along its longitudinal axis in the opposite direction to the proximal (upper) end of the plate. The plate is then adjusted to the flat surfaces of the distal (lower) anchor assembly. The plate is affixed under the connecting plate using two small screws on each end of the connecting plate. Now the whole spring system is assembled.

[0061] Lastly, the secure placement of the anchors is checked and all fixation screws are tightened. The surgeon now sutures the operative wounds in a usual fashion.

[0062] In Vivo Study

[0063] A. Experimental Design and Methods

[0064] This study employs a rabbit model of Adolescent Idiopathic Scoliosis, to characterize the radiographic and morphologic properties of the idiopathic scoliosis.

[0065] 5 rabbits, six weeks old, are separated into 3 groups.

[0066] Young (6 weeks) female New Zealand White rabbits are used to assess the effect of pure rotational forces on the immature spine.

[0067] All animals are individually housed and allowed to acclimate to the facility for days prior to experimental use. The animals survive till full adult size and will be maintained in the animal care facility during the post-operative period for routine feeding and exercise before euthanasia. The animal's general activity, appearance, healing of surgical wounds, weight, and appetite is monitored daily.

[0068] Group No 1: 1 rabbit. The typical right thoracic left lumbar idiopathic scoliotic curve is created by placement of spring-plate implant according to the invention. Implant is removed after curve confirmation by x-ray. The natural behavior of the curve is followed after removal of implant.

[0069] Group No 2: 1 rabbit. The atypical left thoracic right lumbar idiopathic scoliotic curve is created by placement of plate device. Implant is removed after curve confirmation by x-ray. The natural behavior of the curve is followed after removal of implant.

[0070] Group No 3: 3 rabbits. Typical right thoracic left lumbar idiopathic scoliotic curve and opposite curve are created by placement of plate implant in different directions. After confirmation of curve by x-ray the spring-plate device is reoriented in the opposite direction for treatment of mal-curvature. After confirmation of correction of curves by x-ray, the implant is removed and the consistency of improvement is followed after removal of implant.

[0071] Assessment of Magnitude of Scoliotic Curve:

[0072] The magnitude of the scoliotic curve is assessed by radiographic plain x-ray. The amount of rotational changes of the apical vertebra is evaluated by use of CT-scan. The scoliotic curve progression or improvement during follow-up period is assessed initially at the time of surgery and 3 times due growing process and follow-up until achievement by each animal of maturity and full adult size.

[0073] The anatomical changes of the spine are assessed by dissection of each rabbit after euthanasia.

[0074] Surgical Procedure for Human Beings:

[0075] A. Placing the patient in a prone position. Making sure that no excessive pressure exists on the abdomen or on the limbs.

[0076] B. Preparing the patient's back with a surgical soap solution for 5-7 minutes and then with antiseptic solution. The area of the operative site is shaved then draped and plastic steri-drape is used to seal off the skin.

[0077] C. Making straight midline skin incision centered over the apex of the proximal (upper) scoliotic curve. The incision length is approximately along 2-3 spinous processes. Deeping the incision to the level of the spinous processes. Control bleeding with electrocautery.

[0078] D. Exposing the base part of the apical vertebra extraperiosteally from each side of it. Confirm the right location by using of image intensifier. Extending the extraperiosteal dissection sideways from the spinous process keeping the retractors (Weitlaner retractors) tight at all times. Maximally preserve muscles and ligaments around. Continue with dissection and retraction until the middle part of the transverse

process on each side of the apical vertebra is exposed. During exposure try not to damage the branch of segmental vessel located just lateral to each facet.

[0079] E. Placing the self-retaining retractors deeper to hold the entire incision open and exposed. Placing the hook part of the anchor by sliding the tip of it under the base of the transverse process. The direction of the hook insertion may be either proximal (cranial) or distal (caudal). Performing the same procedure on the other side of the vertebra In a case when the surgeon decides to use any other than hook-anchor part, for example screw-anchor part its placement is performed using standard technique for pedicular screw placement.

[0080] F. Checking the security of anchors seating. Fixating the triangular slope-block part, using a small screw, to the flat surface of the anchor located on the convex side of the scoliotic curve.

[0081] G. Pushing the anchors towards the middle line and to each other until they contact above the spinous process of the apical vertebra and intact supraspinous ligament. As both anchors are in contact, make sure that no ligamental tissue is crushed between their docking parts. In case of entrapment, replace the anchors with higher ones in such a way that their docking parts meet above the tip of the spinous process and supraspinous ligament.

[0082] H. Immobilizing both anchors by placing the connecting plate on the upper flat surfaces of the anchors and loosely fixating the connecting plate by two small screws on each end of it.

[0083] I. Performing exactly the same procedure (C-H) through the separate incision on the level of the apical vertebra of the distal (lower) scoliotic curve with one exception: the connecting plate should be fixed only to one anchor located on the concave side of the scoliotic curve. Make sure that the triangular slope-block is located on the opposite side

to the triangular slope-block of the upper anchor assembly, because in case of the double curve the apical parts of the both curves are rotated in the opposite directions.

[0084] J. Making the subcutaneous tunnel between the two operating wounds by blunt dissection under superficial fascia.

[0085] K. Placing the spring-plate into the subcutaneous tunnel. Insert the proximal (upper) end of the spring-plate into the slot under the connecting plate of the anchors assembly and secure the spring-plate to the anchors assembly by tightening of the two small screws. Now the upper part of the spring-plate is secure.

[0086] L. Twisting the distal (lower) end of the spring-plate along its longitudinal axis in the opposite direction to the proximal (upper) end of the spring-plate. Adjusting the spring-plate to the flat surfaces of the distal (lower) anchor assembly. Fixating the spring plate under the connecting plate using two small screws on each end of the connecting plate. Now the whole spring system is assembled.

[0087] M. Checking the security of the anchors and tightening of all the fixation screws. Suturing the operative wounds in usual fashion. Be prepared to the tightness and bulging of the edge of the operating wound above the part of the anchor assembly on the convex side of the scoliotic curve. If the skin edge is difficult to close because of the increased volume of the wound content, make release by gentle full thickness undermining of the edge of the operating wound on the tight side.

[0088] The corneal reflex, heart rate, response to stimuli, and respiration rate are monitored during the operative procedure and post-operative period. Subjects are monitored every 15 minutes for the first two hours post-operatively.

[0089] During this time period, temperature, heart rate/pulse, respiratory rate, activity level and general appearance including surgical site are monitored. After this two-hour period, subjects are checked hourly until 5 p.m. while in the recovery room.

[0090] In rabbit studies, the rabbits are given an injection of Rimadil (1.5 mg/kg SC 6-12 hrs) for analgesia and Cefamezine (40 mg/kg IM) for antibiotic prophylaxis. Injection of Rimadil is repeated in the evening so as to ensure that post-procedural pain is minimized. Animals are monitored daily once the rabbits are judged to be clinically stable by the animal's general activity, appearance, healing of surgical wounds, weight, and appetite.

[0091] The animals survive until full adult size and will be maintained in the animal care facility during the observation period for routine feeding and exercise before euthanasia. Further, the surgery is designed to avoid production of neurological deficit. Animals sustaining neurological deficits will be immediately removed from the study and euthanized

[0092] For euthanasia after achievement of adult size, animals are pre-medicated with Acepromazine 0.1-0.2 mg/kg SC,

[0093] 15 minutes prior to euthanasia. Animals are euthanized with Petobarbitol sodium 150 mg/kg IV bolus. Bilateral thoracotomy is performed to ensure adequacy of euthanasia.

[0094] The animal model of Adolescent Idiopathic Scoliosis was created successfully in accordance with the procedure stipulated above and the scloroitic curve created was moderate.

[0095] The treatment of scoliosis by the implants was successful as determined by x-ray figures (not shown) which demonstrated that the curve was reduced in all animals that

survived back to normal indication the concept of role of rotational component of spinal deformity in scoliosis formation is valid.

[0096] The concept of effectiveness of continuous derotational forces for treatment of scoliosis was proved. The effectiveness of designed device was proved.